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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/800,372	03/12/2004	Yougandh Chitre	A04P1024	8872
36802	7590	01/10/2006	EXAMINER	
PACESETTER, INC. 15900 VALLEY VIEW COURT SYLMAR, CA 91392-9221			JOHNSON, SHEVON ELIZABETH	
			ART UNIT	PAPER NUMBER
			3766	

DATE MAILED: 01/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/800,372

Applicant(s)

CHITRE ET AL.

Examiner

Shevon E. Johnson

Art Unit

3766

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 March 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-14 is/are pending in the application.
- 4a) Of the above claim(s) 1-7 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-12 and 14 is/are rejected.
- 7) ☒ Claim(s) 13 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Response to Arguments

1. This action is in response to applicant's amendment received on 11/3/2005. Claims 1-7 were cancelled without prejudice on 8/30/2005. Examiner withdraws the rejection of claims 8-14 under 35 U.S.C. 112, second paragraph as being indefinite. Claims 8-14 are currently pending in this application.

2. ***Applicant's remarks have been fully considered but they are deemed moot in view of the new grounds of rejection.***

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. **Claim 8 is rejected under 35 U.S.C. 102(b) as being anticipated by Brennen et al. (U.S. Patent No. 5,662,119).**

In regards to claim 8, Brennen et al. discloses a lead implant system comprising: an elongated stylet 10 having an internal passage extending longitudinally through the stylet; a guide wire (pull wire) 12 that is slidably receivable in the longitudinally extending passage of the stylet, the combined stylet and guide wire being configured for slidable introduction into an elongated tubular lead body, and wherein the guide wire is configured for extension from a distal end of the stylet (col. 6, lines 47-65, Fig. 1).

In regards to claim 9, Brennen et al. discloses a lead implant system wherein the stylet is configured to be firmly engaged with a thrusting region of the lead to wedge the distal end of the lead into place at the desired implant location (abstract; col. 3, lines 66 – col. 4, lines 1-3; col. 9, lines 32-37).

5. Claims 8, 9 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Pianca (U.S. Patent No. 6,389,320).

In regards to claim 8, Pianca discloses a lead implant system comprising: an elongated stylet 28 having an internal passage extending longitudinally through the stylet; a guide wire 50 that is slidably receivable in the longitudinally extending passage of the stylet, the combined stylet and guide wire being configured for slidable introduction into an elongated tubular lead body 20, and wherein the guide wire is configured for extension from a distal end of the stylet (col. 4, lines 40-46, Fig. 3; col. 5, lines 19-31, Fig. 6).

In regards to claims 9 and 14, Pianca discloses a lead implant system wherein the stylet is configured to be firmly engaged with a thrusting region of the lead to wedge the distal end of the lead into place at the desired implant location (col. 4, lines 47-55; col. 5, lines 29-31).

6. Claims 8, 9, 12, 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Starksen (U.S. Patent No. 5,571,161).

In regards to claim 8, Starksen discloses a lead implant system comprising: an elongated stylet 60 having an internal passage extending longitudinally through the stylet; a guide wire (G) that is slidably receivable in the longitudinally extending passage of the stylet, the combined stylet and guide wire being configured for slidable introduction into an elongated tubular lead body 10, and wherein the guide wire is configured for extension from a distal end of the stylet (col. 5, lines 35-50, Fig. 8b).

In regards to claim 9 and 14, Starksen discloses a lead implant system wherein the stylet is configured to be firmly engaged with a thrusting region of the lead to wedge the distal end of the lead into place at the desired implant location (col. 5, lines 51-58).

In regards to claim 12, Starksen discloses a lead implant system wherein the stylet includes a ball member 64 at its distal end to reduce the possibility of perforating the vasculature (col. 5, lines 26-34, Figs. 4 and 8B).

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7. Claims 8 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Mobin-Uddin (U.S. Patent No. 4,727,873).

In regards to claims 8 and 14, Mobin-Uddin discloses a lead implant system comprising: an elongated stylet 42 having an internal passage extending longitudinally through the stylet; a guide wire 36 that is slidably receivable in the longitudinally extending passage of the stylet, the combined stylet and guide wire being configured for slidable introduction into an elongated tubular lead body 29, and wherein the guide wire is configured for extension from a distal end of the stylet (col. 4, lines 64-68 – col. 5, lines 1-17, Fig. 8).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pianca (U.S. Patent No. 6,389,320) in view of Samson et al. (Re. 33,911).

In regards to claims 10-11, Pianca discloses a lead implant system substantially as claimed refer 35 U.S.C. 102 (b) rejection given above. Pianca does not disclose a system wherein the guide wire comprises: a proximal shaft or tube and an integral distal coil coaxial with the proximal shaft or tube and extending distally from the proximal shaft or tube. However, Samson et al. teaches a guide wire 11 with a shaft or tube 21 as well as a coil 24. Lacking any criticality, it would have been obvious to anyone skilled in the art to have substituted the guide wire 50 as disclosed by Pianca for the guide wire 11 as taught by Samson et al. in order to provide a small, sturdy and flexible guide wire for easy lead insertion in a desired implant location.

Allowable Subject Matter

10. Claim 13 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Citation of Relevant Prior Art

The prior art made of record and not relied upon but considered pertinent to applicant's disclosure include the following references: Griffin, III (U.S. Patent No. 5,697,965) and Giesy et al. (U.S. Patent No. 4,798,193) which teaches the use of a lead with a stylet or guidewire. Chin et al. teaches the use of a guidewire into a stylet but not in combination with a lead.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shevon E. Johnson whose telephone number is (571) 272-2010. The examiner can normally be reached on M-F (8 a.m. - 4:30 p.m.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shevon Johnson
Art Unit 3766


Robert Pezzuto
Supervisory Patent Examiner
Art Unit 3766